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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/908,884	08/08/1997	XINNIAN DONG	00786/339004	9977
21559	7590	11/14/2003	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			KUBELIK, ANNE R	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	08/908,884	DONG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne R. Kubelik	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2003 and 7 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-13,15-29,36,40-42 and 47-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-13,15-29,36,40-42 and 47-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The specification and claims have been amended as requested in the papers filed 21 April 2003 and 7 August 2003.
2. The claims numbered 43-48, submitted on 21 April 2003 have been renumbered claims 47-52 in accordance with 37 CFR 1.126. Applicant cancelled the original claims 43-46 in the paper filed 10 June 1999. Applicant is reminded that claim numbers from cancelled claims are not reused. Claims 1-2, 4-13, 15-29, 36, 40-42 and 47-54 are pending.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objection***

4. The objection to claims 17-29, 36 and 40-42 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim is withdrawn in light of Applicant's amendments to the claims.

### ***Claim Rejections - 35 USC § 112***

5. Claims 1-2, 4-13 and 15-16 remain rejected and claims 17-29, 36, 40-42 and 47-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 18 October 2002, as applied to claims 1-2, 4-13 and 15-16. Applicant's arguments and the Declaration of

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Dr. Frederick Ausubel, both filed 21 April 2003, have been fully considered but they are not persuasive.

Applicant urges that the Written Description Guidelines states that a representative number of species depends on whether one of skill in the art would recognize that Applicant as in possession of the necessary common attributes or features of members of the genus.

Applicant urges that these common attributes are their characteristic ankyrin repeats (response pg 12).

This is not found persuasive because the ankyrin repeats total about 55 amino acids, while the total length of NPR1 proteins is about 590 amino acids (SEQ ID NO:3 is 593 amino acids long and the putative NPR1 protein from Nicotiana is 588 amino acids long). Thus, ankyrin repeats comprise less than 10% of the total protein length. What is the sequence of the rest of the claimed nucleic acids? Furthermore, the specification does not describe the structural and functional features of the nucleic acids that encode ankyrin-repeat-containing disease resistance proteins that distinguish them from ankyrin-repeat-containing proteins that are not disease resistance proteins. What are the structural features that indicate that a given ankyrin protein-encoding nucleic acid encodes a protein that plays a role in disease resistance? The specification does not teach these; thus Applicant was not in possession of the claimed genus.

The Declaration, which is summarized by the response, states that amino acids 262-289 and 323-371 show homology to a mouse ankyrin protein and ankyrin repeat and the NPR1 protein sequence aligns with mouse ankyrin 3. The Declaration further states that the npr1-1 mutant has a substitution in one of the ankyrin repeats, which Famodu (WO 00/28036) states

shows the repeat is important for function. The Declaration also cites Michaely et al and Bork et al (Declaration pg 2-3 and response pg 13).

This is not found persuasive. The histidine that was altered in the mutant is present in ankyrin repeats from mouse (see Figure 6A); thus, that amino acid NOT is uniquely characteristic of plant NPR1 proteins. Michaely et al and Bork et al could not be considered because they were not sent.

The Declaration, which is summarized by the response, states that the claimed family of disease resistance proteins are readily distinguishable from unrelated ankyrin-repeat containing proteins, which do not have this property. The Declaration further states that it's reasonable to assume that plants other than Arabidopsis have such genes, and Bougri et al (WO 00/70069) teaches such genes from wheat, corn and rice (Declaration pg 3-4 and response pg 13-14).

This is not found persuasive. A likelihood of the presence of a gene in other plants does not describe the structural and functional features of that nucleic acid. The instant specification does not teach the genes from wheat, corn and rice.

Applicant urges that Example 17 of the Written Description Guidelines implies that if there had been at least a partial structure common to the members of the genus, or post-filing evidence of a structural relationship between members of the genus, the written decision requirement would have been satisfied. Applicant thus urges that the instant recitation of an ankyrin repeats satisfies the requirement for a common structural feature, and Bougri teaches that the genes from wheat, corn, rice and Arabidopsis have significant sequence homology in the ankyrin repeats (response pg 14-15).

This is not found persuasive because ankyrin repeats comprise less than 10% of the total length of the proteins encoded by the claimed nucleic acids and those ankyrin repeats are present in a great number of other proteins that did not have AR activity. Sedgwick et al (1999, Trends Biochem. Sci. 24:311-316) teach the ankyrin repeats are found in a wide range of proteins, including inhibitors, developmental regulators, cytoskeleton organizers and toxins and that in most of these proteins ankyrin repeats are combined with unrelated structural modules (pg 311, column 3, paragraph 1). Ankyrin repeats appear to be involved in protein-protein interactions and not in the unique role of the protein (Sedgwick et al, paragraph spanning pg 311-312, and Cao et al, 1997, Cell 88:57-63, pg 61, left column, paragraph 3). What are the common structural features of the non-ankyrin repeats portion of the proteins encoded by the claimed nucleic acids?

The structural features shared by those nucleic acids are not described in the instant case. In Bourgri et al it is the proteins that share homology with the NPR1 protein in the region of ankyrin repeats; homology between the nucleic acids was not demonstrated.

Furthermore, claim 6 is drawn to an NPR1 gene from a *Cruciferae*. The *Cruciferae* comprises at least 162 genera, including *Aethionema*, *Alliaria*, *Alyssum*, *Apophyllum*, *Arabidopsis*, *Arabis*, *Armoracia*, *Atamisquea*, *Aubrieta*, *Aurinia*, *Barbarea*, *Belencita*, *Beringia*, *Berteroa*, *Berteroella*, *Bivonaea*, *Boechera*, *Boleum*, *Boscia*, *Brassica*, *Braya*, *Buchholzia*, *Cadaba*, *Cakile*, *Calepina*, *Camelina*, *Capparis*, *Capsella*, *Cardamine*, *Cardaria*, *Carrichtera*, *Caulanthus*, *Cheesemania*, *Chorispora*, *Cleome*, *Cleomella*, *Cochlearia*, *Cochleariella*, *Coincya*, *Conringia*, *Coronopus*, *Crambe*, *Crambella*, *Crateva*, *Crucihimalaya*, *Cusickiella*, *Dactylaena*, *Dentaria*, *Descurainia*, *Dichasanthus*, *Dimorphocarpa*, *Diplotaxis*, *Dipterygium*, *Dithyrea*,

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*Draba, Drabopsis, Dryopetalon, Erophila, Eruca, Erucastrum, Erysimum, Euadenia, Eutrema, Euzomodendron, Forchhammeria, Fortuynia, Gaggria, Guillenia, Guiraoa, Gynandropsis, Halimolobos, Hemisrambe, Hilliella, Hirschfeldia, Hornungia, Hymenolobus, Ianhedgea, Iberis, Ionopsidium, Isatis, Ischnocarpus, Isomeris, Iti, Jonopsidium, Kerneria, Kremeriella, Leavenworthia, Lepidium, Lesquerella, Lobularia, Lunaria, Lyrocarpa, Maerua, Mancoa, Matthiola, Megacarpaea, Microthlaspi, Moricandia, Morisonia, Mostacillastrum, Muricaria, Nasturtium, Neobeckia, Neotorularia, Nerisyrenia, Nerisyrenia linearifolia, Neslia, Noccidium, Notothlaspi, Olimarabidopsis, Orychophragmus, Oxystylis, Pachycladon, Pachyphragma, Peltaria, Pennellia, Physaria, Physorhynchus, Podandrogyne, Polanisia, Polystenium, Pringlea, Pritzelago, Pseudoarabidopsis, Psychine, Raphanus, Rapistrum, Rhizobotrya, Ritchiea, Romanschulzia, Rorippa, Savignya, Schivereckia, Schoenocrambe, Schouwia, Sibara, Sinapidendron, Sinapis, Sisymbrium, Smelowskia, Sphaerocardamum, Stanleya, Steriphoma, Streptanthella, Streptanthus, Succowia, Synthlipsis, Teesdalia, Thellungiella, Thelypodopsis, Thelypodium, Thlaspi, Thylachium, Thysanocarpus, Vania, Vella, Warea, Werdermannia, Wislizenia, Yinshania, and Zilla; these genera total hundreds, if not thousands of species (See <http://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi>). the specification describes exactly one NPR1 gene (SEQ ID NO:1) from one of these species, *Arabidopsis thaliana*.*

Claim 5 is drawn to an NPR1 gene from a *Solanaceae*. The *Solanaceae* comprises at least 57 genera, including *Anisodus, Anthocercis, Anthotroche, Athenaea, Atropa, Aureliana, Brachistus, Browallia, Brunfelsia, Capsicum, Cestrum, Coeloneurum, Crenidium, Cuatresia, Cyphanthera, Datura, Deprea, Duboisia, Duckeodendron, Espadaea, Goetzea, Goetzia, Grabowskia, Grammosolen, Henoonia, Hyoscyamus, Jaborosa, Jaltomata, Juanulloa, Larnax,*

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*Lycianthes, Lycium, Mandragora, Metternichia, Nicandra, Nicotiana, Nierembergia, Nolana, Normania, Petunia, Physalis, Salpiglossis, Saracha, Schizanthus, Schwenckia, Scopolia, Sessea, Solandra, Solanum, Lycopersicon, Symonanthus, Triguera, Tubocapsicum, Vassobia, Vestia, Withania, and Witheringia*; these genera total hundreds, if not thousands of species (see <http://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi>). The specification describes exactly one NPR1 gene (SEQ ID NO:13) from one of these species, *Nicotiana glutinosa*.

The specification in describing one, or potentially two nucleic acids, that fall within the claims, does not describe a representative number of nucleic acids within that scope, given the thousands and thousands of plants species and given that Applicant recites only one common structural feature that is also present in a vast number of non-NPR-proteins.

*See In re Shokal*, 113 USPQ 283, (CCPA 1957) at pg 285

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary. ...

We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

6. Claims 1-2, 4-13 and 15-16 remain rejected and claims 17-29, 36, 40-42 and 47-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for NPR1 coding sequences from *Arabidopsis* that comprise SEQ ID NOs: 1 and 2, does not reasonably provide enablement for any nucleic acid that encodes an ankyrin-repeat-containing disease resistance protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention



commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 18 October 2002, as applied to claims 1-2, 4-13 and 15-16. Applicant's arguments and the Declaration of Dr. Frederick Ausubel, both filed 21 April 2003, have been fully considered but they are not persuasive.

Applicant urges that the specification clearly enables the claimed subject matter simply by providing Applicant's NPR1 sequence. The Declaration, which is summarized by the response, states that genes falling within the scope of the claims could be isolated and identified from a variety of plant sources using nothing more than standard techniques of molecular biology; instructions for isolation are on pg 50-52 of the specification. The Declaration states that any experimentation involved is straightforward and simply requires use of the disclosed NPR1 sequence as probes in gene screening methods, methods which have been used routinely for over 20 years. The Declaration cites Grunstein et al, Benton et al and Sanger et al as examples that teach the basic methodologies (Declaration pg 4-6 and response pg 16-17).

This is not found persuasive because an assay for finding a product is not equivalent for a positive recitation for how to make a product; the specification fails to teach how to make the claimed nucleic acids because it does not teach the structure of the claimed nucleic acids. If finding the claimed nucleic acids was so routine and straightforward, why aren't the sequences in the specification?

Applicant urges that *in re Wands* makes it clear that enablement is not negated by the necessity for experimentation and screening gene libraries is routine (response pg 18).

This is not found persuasive because experimentation and screening is useful for distinguishing between inoperative and operative embodiments; however, a teaching of how to find is not a teaching of how to make.

The Declaration, which is summarized by the response, states that the specification teaches the isolation of an AR gene from tobacco and the protein encoded by this gene has an ankryn repeat (Declaration pg 6-7 and response pg 18-19).

This is not found persuasive because the specification does not teach the structural and functional features of the nucleic acids that encode ankyrin-repeat-containing disease resistance proteins that distinguish them from ankyrin-repeat-containing proteins that are not disease resistance proteins.

The presence of an ankyrin repeat does not mean a protein plays a role in plant disease resistance. Sedgwick et al (1999, Trends Biochem. Sci. 24:311-316) teach the ankyrin repeats are found in a wide range of proteins, including inhibitors, developmental regulators, cytoskeleton organizers and toxins and that in most of these proteins ankyrin repeats are combined with unrelated structural modules (pg 311, column 3, paragraph 1). Ankyrin repeats appear to be involved in protein-protein interactions and not in the unique role of the protein (Sedgwick et al, paragraph spanning pg 311-312, and Cao et al, 1997, Cell 88:57-63, pg 61, left column, paragraph 3).

The specification does not teach the other structural motifs that would enable one to identify which nucleic acids that encode ankyrin-repeat containing proteins encodes proteins that confer disease resistance upon a plant.

The Declaration, which is summarized by the response, states that the data strongly corroborate the assertion that structurally related gene sequences falling within the scope of the claims exists and that they may be identified and isolated from a variety of plant sources using applicant's NPR1 sequence and standard techniques, as others have done (Declaration pg 7 and response pg 19).

This is not found persuasive because the specification does not teach how to make the claimed genes, *i.e.*, do not teach the sequence of the genes.

The Declaration, which is summarized by the response, states that the specification on pg 69 teaches the ability of a structurally related gene to confer plant disease is easily established using a variety of methods, and the specification on pg 45-46 teaches that plants transformed with the *Arabidopsis* gene are resistant to bacterial and fungal pathogens (Declaration pg 7-8 and response pg 19-20).

This is not found persuasive. The ability of the *Arabidopsis* gene to confer pathogen resistance on plants is not in question. The specification does not teach the structural and functional features of the nucleic acids that encode ankyrin-repeat-containing disease resistance proteins that distinguish them from ankyrin-repeat-containing proteins that are not disease resistance proteins.

The Declaration, which is summarized by the response, states that Bougri's ankyrin repeats containing NPR homologs promote resistance against pathogens and that each of Crane et al (US 6,505,084) and Famodu et al identified AR sequences based on their homology to the NPR1 gene. Thus, the Declaration states there is no scientific reason to doubt the existence of the claimed gene family (Declaration pg 8-10 and response pg 20-23).

This is not found persuasive because a likelihood of the presence of a gene in other plants does not teach the structural features of that nucleic acid. The instant specification does not teach the genes from wheat, corn and rice.

Applicant urges that the maize, wheat and rice NPR homologs were identified using knowledge of the Arabidopsis NPR gene and gene isolation methods known at the time Applicant's application was filed and no methods developed after filing were used. Applicant urges that art appearing after filing can be used as evidence of enablement (response pg 22-23).

This is not found persuasive because the specification only teaches how to find the claimed nucleic acids. A teaching of how to find is not a teaching of how to make. The specification does not teach the structural and functional features of the nucleic acids that encode ankyrin-repeat-containing disease resistance proteins that distinguish them from ankyrin-repeat-containing proteins that are not disease resistance proteins.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

See *Plant Genetic Systems N.V. v. DeKalb Genetics Corp.*, 65 USPQ2d 1452 (CA FC 2003), which states that a "[p]atent claiming [a] 'pioneering' invention is not entitled to lowered standard for meeting enablement requirement of 35 U.S.C. §112."

Applicant urges that even if not every nucleic acid falling within the claims confers disease resistance, it does not mean the claims are overbroad as nonoperative embodiments are permitted. Applicant urges that one of skill in the art could easily screen structurally related

genes using standard techniques to determine the level of resistance and that this situation is indistinguishable from Wands (response pg 23-24).

This is not found persuasive. The specification does not teach the structural and functional features of the nucleic acids that encode ankyrin-repeat-containing disease resistance proteins that distinguish them from ankyrin-repeat-containing proteins that are not disease resistance proteins

Applicant urges that *Ex Parte Chen* states that a specification was enabling for integration of a gene into fish embryos even though the method had a 1% success rate. Applicant urges that the Office has not offered any evidence that undue experimentation would be required to practice the claimed invention and that the Office must establish a reasonable basis to question the enabling nature of a specification (response pg 24-26).

This is not found persuasive. *Ex Parte Chen* is not comparable to the instant case. In *Ex Parte Chen*, the question was whether a method of transformation using a gene of known sequence was enabled. In the instant case the sequence of the gene is not known, thus plants transformed with the gene are not enabled. The claims are not enabled because the specification does not teach the structural features of the claimed genes.

The specification fails to provide evidence that the *N. glutinosa* nucleic acid SEQ ID NO: 13 encodes a protein that confers disease resistance to a plant expressing the protein and has a functional relatedness to the Arabidopsis NPRI gene. Applicant is encouraged to submit a declaration providing data that shows that SEQ ID NO:13, when transformed into a plant, confers disease resistance on the plant. This declaration would not however, enable the full scope of the instant claims.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 10-13, 15-29, 36, 40-42 and 47-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 10-12 17, 22, 36 and 40 are indefinite in their recitation of "hybridizes". The hybridization conditions are not defines; thus it is unclear which nucleic acids fall within the claims.

In claim 28, it is unclear if the seed comprises the nucleic acid or vector.

In claim 40, part (a), word(s) appear to be missing in the recitation of "producing a transgenic plant cell (i) an isolated nucleic acid molecule". Should --comprising-- be inserted after "cell"?

***Claim Rejections - 35 USC § 102***

9. Claims 1-2, 4-13 and 15-16 remain rejected and claims 17-29, 36, 40-42 and 47-54 are rejected under 35 U.S.C. 102(c) as being anticipated by Ryals et al (US Patent 6,091,004, filed June, 1996). The rejection is repeated for the reasons of record as set forth in the Office action mailed 18 October 2002, as applied to claims 1-2, 4-13 and 15-16. Applicant's arguments filed 21 April 2003 have been fully considered but they are not persuasive.

Applicant urges that they believe they are the first to invent the claimed subject matter and that an interference should be declared (response pg 27).

This is not found persuasive. An interference cannot be declared until all other issues in the case are resolved. Additionally, Applicant must request an interference under 37 CFR 1.607 and make a showing under 37 CFR 1.608(a). See MPEP 2307 and 2308.

### ***Double Patenting***

10. Claims 1-2, 4-13 and 15-16 remain provisionally rejected and claims 17-29, 36, 40-42 and 47-54 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-25 of copending Application No. 09/908,323. The rejection is repeated for the reasons of record as set forth in the Office action mailed 18 October 2002, as applied to claims 1-2, 4-13 and 15-16. Applicant's arguments filed 21 April 2003 have been fully considered but they are not persuasive.

Applicant urges that a terminal disclaimer will be filed when allowable subject matter is determined (response pg 27). This is acknowledged.

### ***Conclusion***

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm. Sometime in January 2004, the examiner's phone number will change to (571) 272-0801.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.  
November 11, 2003

